



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2019-0075; FRL-9991-20]

Certain New Chemicals; Receipt and Status Information for January 2019

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is required under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to make information publicly available and to publish information in the **Federal Register** pertaining to submissions under TSCA Section 5, including notice of receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN) or Microbial Commercial Activity Notice (MCAN), including an amended notice or test information; an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or concluded; a notice of commencement (NOC) of manufacture (including import) for new chemical substances; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review. This document covers the period from 01/01/2019 to 01/31/2019.

DATES: Comments identified by the specific case number provided in this document must be received on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2019-0075, and the specific case number for the chemical substance related to your comment, by one of the following methods:

• *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Jim Rahai, Information Management Division (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8593; email address: rahai.jim@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

This document provides the receipt and status reports for the period from 01/01/2019 to 12/31/2019. The Agency is providing notice of receipt of PMNs, SNUNs and MCANs (including

amended notices and test information); an exemption application under 40 CFR part 725 (Biotech exemption); TMEs, both pending and/or concluded; NOCs to manufacture a new chemical substance; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review.

EPA is also providing information on its web site about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its web site at:

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices>. This information is updated on a weekly basis.

B. What is the Agency's authority for taking this action?

Under the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.*, a chemical substance may be either an “existing” chemical substance or a “new” chemical substance. Any chemical substance that is not on EPA's TSCA Inventory of Chemical Substances (TSCA Inventory) is classified as a “new chemical substance,” while a chemical substance that is listed on the TSCA Inventory is classified as an “existing chemical substance.” (See TSCA section 3(11).) For more information about the TSCA Inventory go to: *<https://www.epa.gov/tsca-inventory>*.

Any person who intends to manufacture (including import) a new chemical substance for a non-exempt commercial purpose, or to manufacture or process a chemical substance in a non-exempt manner for a use that EPA has determined is a significant new use, is required by TSCA section 5 to provide EPA with a PMN, MCAN or SNUN, as appropriate, before initiating the

activity. EPA will review the notice, make a risk determination on the chemical substance or significant new use, and take appropriate action as described in TSCA section 5(a)(3).

TSCA section 5(h)(1) authorizes EPA to allow persons, upon application and under appropriate restrictions, to manufacture or process a new chemical substance, or a chemical substance subject to a significant new use rule (SNUR) issued under TSCA section 5(a)(2), for “test marketing” purposes, upon a showing that the manufacture, processing, distribution in commerce, use, and disposal of the chemical will not present an unreasonable risk of injury to health or the environment. This is referred to as a test marketing exemption, or TME. For more information about the requirements applicable to a new chemical go to:

<http://www.epa.gov/oppt/newchems>.

Under TSCA sections 5 and 8 and EPA regulations, EPA is required to publish in the **Federal Register** certain information, including notice of receipt of a PMN/SNUN/MCAN (including amended notices and test information); an exemption application under 40 CFR part 725 (biotech exemption); an application for a TME, both pending and concluded; NOCs to manufacture a new chemical substance; and a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review.

C. Does this action apply to me?

This action provides information that is directed to the public in general.

D. Does this action have any incremental economic impacts or paperwork burdens?

No.

E. What should I consider as I prepare my comments for EPA?

1. *Submitting confidential business information (CBI).* Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or email. Clearly mark the part or all of the information that you

claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Status Reports

In the past, EPA has published individual notices reflecting the status of TSCA section 5 filings received, pending or concluded. In 1995, the Agency modified its approach and streamlined the information published in the **Federal Register** after providing notice of such changes to the public and an opportunity to comment (See the **Federal Register** of May 12, 1995, (60 FR 25798) (FRL-4942-7). Since the passage of the Lautenberg amendments to TSCA in 2016, public interest in information on the status of section 5 cases under EPA review and, in particular, the final determination of such cases, has increased. In an effort to be responsive to the regulated community, the users of this information, and the general public, to comply with the requirements of TSCA, to conserve EPA resources and to streamline the process and make it more timely, EPA is providing information on its web site about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its web site at:

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notice>. This information is updated on a weekly basis.

III. Receipt Reports

For the PMN/SNUN/MCANs that have passed an initial screening by EPA during this period, Table I provides the following information (to the extent that such information is not subject to a CBI claim) on the notices screened during this period: The EPA case number assigned to the notice that indicates whether the submission is an initial submission, or an amendment, a notation of which version was received, the date the notice was received by EPA, the submitting manufacturer (i.e., domestic producer or importer), the potential uses identified by the manufacturer in the notice, and the chemical substance identity.

As used in each of the tables in this unit, (S) indicates that the information in the table is the specific information provided by the submitter, and (G) indicates that this information in the table is generic information because the specific information provided by the submitter was claimed as CBI. Submissions which are initial submissions will not have a letter following the case number. Submissions which are amendments to previous submissions will have a case number followed by the letter "A" (e.g. **P-18-1234A**). The version column designates submissions in sequence as "1", "2", "3", etc. Note that in some cases, an initial submission is not numbered as version 1; this is because earlier version(s) were rejected as incomplete or invalid submissions. Note also that future versions of the following tables may adjust slightly as the Agency works to automate population of the data in the tables.

Table I. – PMN/SNUN/MCANs Approved* from 01/01/2019 to 01/31/2019

Case No.	Version	Received Date	Manufacturer	Use	Chemical Substance
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J-19-0012	1	1/14/2019	CBI	(G) Ethanol Production	(G) Biofuel producing <i>Saccharomyces cerevisiae</i> modified, genetically stable
J-19-0013	1	1/14/2019	CBI	(G) Ethanol Production	(G) Biofuel producing <i>Saccharomyces cerevisiae</i> modified, genetically stable
J-19-0014	1	1/14/2019	CBI	(G) Ethanol Production	(G) Biofuel producing <i>Saccharomyces cerevisiae</i> modified, genetically stable
J-19-0015	1	1/14/2019	CBI	(G) Ethanol Production	(G) Biofuel producing <i>Saccharomyces cerevisiae</i> modified, genetically stable
P-19-0031	2	12/28/2018	CBI	(S) Curing agent for epoxy coating systems	(G) Phenol, 4,4'-(1-methylethylidene)bis-, polymer with formaldehyde, 2-(chloromethyl)oxirane, alpha-hydro-omega-hydroxypoly(oxy-1,2-ethanediyl), and polyamines
P-19-0032	3	12/19/2018	Presidium USA, Inc.	(G) Polyol used in the manufacture of articles made of a polyurethane thermoset material	(G) Carbonic dichloride, polymer with 4,4'-(1-methylethylidene)bis[p henol] ester, polymer with tetrol and polyether tetrol
P-19-0045	1	12/21/2018	CBI	(G) Component of textile coating	(G) Non-metal tetrakis (hydroxyalkyl)-, halide, polymer with amide oxidized
P-19-0046	1	1/2/2019	Kluber Lubrication North America L.P.	(G) Lubricating agent	(G) Aromatic polycarboxylic acid, alkyl (C ₈ -C ₁₀) esters

P-19-0047	1	1/2/2019	US Polymers Accurez LLC	(S) Binder for Thermoplastic Coatings	(S) Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymer with 5-amino-1,3,3-trimethylcyclohexanemethanamine, alpha-hydro-omega-hydroxypoly(oxy-1,4-butanediyl), alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane and 1,1'-methylenebis[4-isocyanatobenzene]
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*The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission prior to the start of the 90 day review period, and in no way reflects the final status of a complete submission review.

In Table II. of this unit, EPA provides the following information (to the extent such information is not subject to a CBI claim) on the test information received by EPA during this time period: The EPA case number assigned to the test information; the date the test information was received by EPA, the type of test information submitted, and chemical substance identity.

Table II. – Test Information Received from 01/01/2019 to 01/31/2019

Case No.	Received Date	Type of Test Information	Chemical Substance
P-00-0281	12/4/2018	Fish Acute Toxicity (OECD 203) Invertebrate Acute Toxicity (Fathead minnows), Algae Toxicity (Raphidocelis subcapitata)	(G) Alkarylsulfonic acid, sodium salts
SN-17-0011	12/4/2018	Whole Body (Inhalation) 2 Generation Reproductive Toxicity Study and Workplace Air Monitoring and Exposure Modeling Study	(G) Polyfluorohydrocarbon

P-87-1436	12/6/2018	<p>QSAR Assessment Report on Vinyl Laurate; Skin Sensitization: Local Lymph Node Assay (OECD TG 429); Repeated Does 90-Day Oral Toxicity in Rodents (OECD TG 408); Repeated Dose Toxicity and Repro/Devel Toxicity Screening (OECD TG 422); Chromosome Aberration Test (OECD TG 473); Gene Mutation Assay (OECD TG 476); Micronucleus Test (OECD TG 474); Prenatal Developmental Toxicity Study (OECD TG 414); Aquatic Toxicity – Daphnia (OECD TG 202); Aquatic Toxicity – Daphnia Reproductive (OECD TG 211); Aquatic Toxicity – Algal Growth (OECD TG 201); Ready Biodegradability (OECD TG 301); Dermal Irritation/Corrosion (OECD TG 404); Bacterial Reverse Mutation Assay – Ames Test (OECD 471); Fish Acute Toxicity (OECD TG 203); Activated Sludge Test (OECD TG 209); Acute Oral Toxicity (OECD TG 401); Acute Eye Irritation (OECD TG 405); Acute Dermal Toxicity (OECD TG 402). Note: There are no additional processing and use requests beyond the original PMN, except for allowing our site limited use as a monomer in polymer production.</p> <p>Added commentary on EPA Risk Assessment.</p>	(S) Dodecanoic acid, ethenyl ester
P-11-0483	12/7/2018	Routine/Annual Testing and Reporting: Certifications of Analysis	(G) Alkyl thiol
P-11-0484	12/7/2018	Routine/Annual Testing and Reporting: Certifications of Analysis	(G) Alkyl sulfate salt
P-11-0487	12/7/2018	Routine/Annual Testing and Reporting: Certifications of Analysis	(G) Alkyl polyamide
P-11-0527	12/7/2018	Routine/Annual Testing and Reporting: Certifications of Analysis	(G) Substituted fluoroalkane
P-11-0528	12/7/2018	Routine/Annual Testing and Reporting: Certifications of Analysis	(G) Fluorinated thiol
P-11-0529	12/7/2018	Routine/Annual Testing and Reporting: Certifications of Analysis	(G) Fluorinated monomer
P-11-0530	12/7/2018	Routine/Annual Testing and Reporting: Certifications of Analysis	(G) Fluoropolyacrylamide
P-11-0532	12/7/2018	Routine/Annual Testing and Reporting: Certifications of Analysis	(G) Polyfluoroalkyl amine

P-11-0533	12/7/2018	Routine/Annual Testing and Reporting: Certifications of Analysis	(G) Non-ionic fluorosurfactant
P-11-0534	12/7/2018	Routine/Annual Testing and Reporting: Certifications of Analysis	(G) Anionic fluorosurfactant
P-11-0543	12/7/2018	Routine/Annual Testing and Reporting: Certifications of Analysis	(G) Polyfluorinated alkyl quaternary amine chloride
P-18-0382	12/10/2018	Consumer Exposure Data	(G) Xanthylum, bis[dicarboxycyclic]sulfonamino-alkylcyclicamino-disulfo-sulfocyclic-, inner salt, monocationic salt
P-17-0115	12/11/2018	Skin Sensitization: Local Lymph Node Assay (OECD Test Guideline 429)	(G) Aminoalkyl alkoxysilane
P-17-0337	12/12/2018	Industrial Hygiene Monitoring Report	(S) Aluminum cobalt lithium nickel oxide

If you are interested in information that is not included in these tables, you may contact EPA's technical information contact or general information contact as described under **FOR FURTHER INFORMATION CONTACT** to access additional non-CBI information that may be available.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: March 19, 2019.

Pamela Myrick,

Director,

Information Management Division,

Office of Pollution Prevention and Toxics.

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